



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/586,747

06/02/2000

Paul R. Burnett

Army 105

7935

30951

7590

05/15/2008

NASH & TITUS, LLC

21402 UNISON RD

MIDDLEBURG, VA 20117

EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/586,747 | BURNETT ET AL. | |
| | Examiner | Art Unit | |
| | Shengjun Wang | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The supplemental reissue declaration and the amendments submitted February 20, 2008 have been fully considered, But are not persuasive to the application in conditions for allowance for reasons set forth below.

Claim Rejections 35 U.S.C 251

1. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because the errors recited in the supplemental reissue declaration are not error(s) correctable by reissue application.
2. Claims 1-14 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

Note, error correctable by reissue application in the claims are is that patent claims 7 and 11 are duplicates.

A supplemental declaration simply states that the patent is wholly or partly invalid because patent claim 11 is a duplicate of patent claim 7, such statement of error would support the reissue.

Objections to claims and Disclosure

3. Pursuant to 37 CFR 1.173(c), each amendment submitted must set forth the status of all patent claims and all added claims as of the date of the submission. The status to be set forth is whether the claim is original , pending or canceled. The failure to submit the claim status will generally result in a notification to applicant that the amendment prior to

Art Unit: 1617

final rejection is not completely responsive (see 37 CFR 1.135(c)). Such an amendment after final rejection will not be entered.

The last set of claims do not provide the status of all claims as of the date of amendment, of all the pending, amended and deleted claims pursuant to 37 CFR

1.173(b)(c) (d).

b) Making amendments in a reissue application . An amendment in a reissue application is made either by physically incorporating the changes into the specification when the application is filed, or by a separate amendment paper. If amendment is made by incorporation, markings pursuant to paragraph (d) of this section must be used. If amendment is made by an amendment paper, the paper must direct that specified changes be made, as follows:

(1) Specification other than the claims . Changes to the specification, other than to the claims, must be made by submission of the entire text of an added or rewritten paragraph, including markings pursuant to paragraph (d) of this section, except that an entire paragraph may be deleted by a statement deleting the paragraph without presentation of the text of the paragraph. The precise point in the specification must be identified where any added or rewritten paragraph is located. This paragraph applies whether the amendment is submitted on paper or compact disc (see §§ 1.52(e)(1) and 1.821(c), but not for discs submitted under § 1.821(e)).

(2) Claims . An amendment paper must include the entire text of each claim being changed by such amendment paper and of each claim being added by such amendment paper. For any claim changed by the amendment paper, a parenthetical expression “amended,” “twice amended,” etc., should follow the claim number. Each changed patent claim and each added claim must include markings pursuant to paragraph (d) of this section, except that a patent claim or added claim should be canceled by a statement canceling the claim without presentation of the text of the claim.

(3) Drawings. One or more patent drawings shall be amended in the following manner: Any changes to a patent drawing must be submitted as a replacement sheet of drawings which shall be an attachment to the amendment document. Any replacement sheet of drawings must be in compliance with § 1.84 and shall include all of the figures appearing on the original version of the sheet, even if only one figure is amended. Amended figures must be identified as “Amended,” and any added figure must be identified as “New.” In the event that a figure is canceled, the figure must be surrounded by brackets and identified as “Canceled.” All changes to the drawing(s) shall be explained, in detail, beginning on a separate sheet accompanying the papers including the amendment to the drawings.

(i) A marked-up copy of any amended drawing figure, including annotations

Art Unit: 1617

indicating the changes made, may be included. The marked-up copy must be clearly labeled as "Annotated Marked-up Drawings" and must be presented in the amendment or remarks section that explains the change to the drawings.

(ii) A marked-up copy of any amended drawing figure, including annotations indicating the changes made, must be provided when required by the examiner.

(c) Status of claims and support for claim changes . Whenever there is an amendment to the claims pursuant to paragraph (b) of this section, there must also be supplied, on pages separate from the pages containing the changes, the status (i.e., pending or canceled), as of the date of the amendment, of all patent claims and of all added claims, and an explanation of the support in the disclosure of the patent for the changes made to the claims.

(d) Changes shown by markings . Any changes relative to the patent being reissued which are made to the specification, including the claims, upon filing, or by an amendment paper in the reissue application, must include the following markings:

(1) The matter to be omitted by reissue must be enclosed in brackets; and

(2) The matter to be added by reissue must be underlined, except for amendments submitted on compact discs (§§ 1.96 and 1.821(c)). Matter added by reissue on compact discs must be preceded with "<U>" and end with "</U>" to properly identify the material being added.

Note the mark-up should show the change from the original issued claims, not the amended claims. In the claims submitted 02/20/2008 Claims 1, 3, 5, 13 are not marked to show the all changes from the originally issued claims. e.g., "poly(DL-lactide-co-glycolide) as" in line 3 of claim 1 was "poly(DL-lactide-co-glycolideas" such change should be marked. Applicants are required to submit the claims showing all the changes compared to the originally issued claims.

Further, following informalities and/or error need to be corrected:

In claim 3, line 1 the word "claims" should be replaced with "claim" ; claim 2 now recites PLGA, as opposed to PLG of original claim issued. no apparent reason to change PLG to PLGA (first appeared in the amendment of 6-27-06)

Art Unit: 1617

Claim 4 of the last set of claims (2-20-08) is missing the word "said" on line 4

Claim 9, line 3 should read 5 microns to 10 microns, to be consistent and not vague. this
Claim (amendment of 12-11-07) again refers to compositions of claim 5. it should be
composition

Claim 7 (amendment of 12-11-07) again refers to compositions of claim 5. it should be
composition. The same is observed in claim 11 referring to claim 6.

Claim 14, line 3 should read 5 microns to 10 microns, to be consistent and not vague.

The amendments of the specification (2/20/2008) are objected as the amendments
should recite the whole paragraph:

FIG. 1 indicates [control] cytotoxic T lymphocyte induction in mice immunized with rgp
160; and

FIG. 2 indicates "Native"/denatured rgp 120 (IIIB) Binding Ratios.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Shengjun Wang whose telephone number is (571) 272-
0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30
pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone

Art Unit: 1617

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617